Effects of visual stimulation and visual training on children with visual impairment

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON31725

Source
ToetsingOnline

Brief title
EVST

Condition

- Vision disorders

Synonym
low vision, visual impairment

Research involving
Human

Sponsors and support

Primary sponsor: Katholieke Universiteit Nijmegen
Source(s) of monetary or material Support: ZONMW stichting InZicht

Intervention

Keyword: rehabilitation, visual impairment, visual stimulation, visual training

Outcome measures

Primary outcome

In accordance with the recommendations of the commission the dependent

variables in both studies will be measured at different levels of visual

function, that is:

- standard measures of visual functioning (grating acuity, contrast

sensitivity, recognition acuity, field of vision by confrontation method)

- behavioural measures of visual functions (scale for Near Detection Vision)

- measures of visual perceptual functioning (imitation of smile)

Secondary outcome

Study 1:

- measures of cognitive development at t0 and t3 (e.g. Reynell-Zinkin scales)

- measures of parent-child interaction at t0 and t3 (Emotional Availability

Scales of Biringen, 1998).

Study 2:

- task completion (reaction time and failure or success)

Study description

Background summary

In March 2006 the InSight foundation invited as to apply for a research grant
to study the effectiveness of visual stimulation for children with visual

impairment.
The invitation mentioned the following commission.
*Insight invites you to design a study on the effectiveness of visual stimulation in children up till the age of 8 with ocular or cerebral visual impairment with or without intellectual disabilities. The intervention should consist of methods, materials, and visual tasks currently in use by early intervention service providers. The intervention will be implemented according to a standard protocol. Consensus on the
content of this 'standard intervention' could be determined by an expert meeting."
With the help of several experts in the Netherlands a proposal for two studies has been designed.

Study objective

The goal is to study the effectiveness of visual stimulation in children up till the age of 8 with ocular or cerebral visual impairment with or without intellectual disabilities.
Since the commission explicitly stated that the intervention should consist of methods, materials, and visual tasks currently in use by early intervention service providers, one of the targets will be to first build consensus on a standard intervention protocol.

As a result of this multi stage design the definitive choice of dependent variables can only be made after the consensus meeting has been held.

Study design

Study 1:
The intervention will take place in an experimental control group design with a pre-test (t0), one intermittent (t1), one post test (t2), and one follow up test (t3). Tests will be performed by the researcher with intervals of four months. Duration of the training will be 8 months. The children will be randomly assigned to the treatment or control group. Children in both the treatment and control group will receive normal early intervention services. Children in the control
group will receive the common standard intervention with regard to visual training but not an individualized visual training program, the latter is only given to the children in the experimental group.

Study 2:
Training of several tasks to one individual and/or the same tasks to several subjects will be given by a trained MSc-student after a comprehensive assessment of the child*s competencies and relevant tasks.
Training procedures will be in accordance with Hall Lueck (2004), Hall and Bailey (1989) and Hall Lueck, Dornbusch, & Hart (1999) and will be applied in a

nonconcurrent multiple baseline across variables and subjects design.

Intervention

The first study will concern the effectiveness of visual stimulation in young children in early intervention programs. The content of the intervention will be based on previous studies of the Institute of Child Health of the Great Ormond Street Hospital for Sick Children (Sonksen, Petrie, & Drew, 1991). This program was chosen because it proved to be effective with children in the UK and it seems to be suitable to current early intervention practices in the Netherlands, mostly because several aspects of the intervention are already in use. The exact content, assessment procedures, and as a consequence the number and kind of dependent variables will be determined in a consensus meeting. Professor Sonksen and collegues of the Institute of Child Health UCL has kindly agreed to participate in this meeting and helped us to choose intervention and variables for the study. In the meantime we have decided to apply the "record of developing vision" and the accompanying activity cards from the Developmental Journal for babies and children with visual impairment. This program is not in us with any of the institutes in the Netherlands.

The second study concerns children 4 years and older. With these children training can also be conducted at their schools, which may make it possible to have daily training sessions. The procedures described by Hall Lueck, Dornbusch and Hart (1999), Hall and Bailey (1989) and Hall Lueck (2004) will be used. In this kind of training a topdown approach for choosing intervention effects is used. Critical and relevant tasks given the child*s competencies, likes, dislikes and needs, and the parent*s and teacher*s priorities are chosen. Visual training is part of a larger intervention program and certainly not a goal in itself. The effectiveness of this intervention will be the subject of study 2.

Hall Lueck, A. (2004). Functional Vision, a practitioner's guide to evaluation and intervention. New York: AFB Press.
Hall, A., & Bailey, I. L. (1989). A model for training vision functioning. Journal of Visual Impairment & Blindness, 83, 390-396.
Hall Lueck, A., Dornbusch, H., & Hart, J. (1999). The effect of training on a young child with cortical visual impairment: an exploratory study. Journal of Visual Impairment & Blindness, 93, 778-793.
Sonksen PM, Petrie A, & Drew KJ. (1991). Promotion of visual development of severely visually impaired babies: evaluation of a developmentally based program. Developmental Medicine and Child Neurology. 33, 320-335.

Study burden and risks

Burden:

For child and one parent four home visits of 1 hour. Two orthoptic examinations of 30 minutes.

Risk:
Time devoted to the intervention cannot be devoted to other activities.

Research justified:
Visual stimulation and visual training are commonly used in early intervention programs for children with visual impairments. There is no standard intervention and often intervention are applied that have no proven effect. As we described in our article (Vervloed, M.P.J., Janssen, N. & Knoors, H. (2006). Visual rehabilitation of children with visual impairment. Journal of Developmental and Behavioral Pediatrics, 27, 6, 493-506.) there are interventions that seem to be useful but the empirical evidence is still weak, so no definite conclusions can be drawn regarding visual stimulation and training.
The current study tries to enlarge this empirical evidence and to come up with standards and protocols for rather arbitrarily applied intervention regarding visual stimulation and training. Research by a population other than children with visual impairments is useless, that is why the population as described above will be studied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Study 1:
1. ocular or cerebral or cortical visual impairment
2. visual acuities between light perception and 3/10
3. Developmental age less then 24 months at the start of the intervention
4. congenitally or perinatally acquired impairments ;Study 2:
Five participants will be included who comply with the same criteria as in study 1 with the exception that the maximum chronological age is 8 instead of 4 years

Exclusion criteria

Study 1:
1. previously received intervention with regard to visual training or visual stimulation
2. acquired visual impairments
3. progressive or neurodegenerative impairments;Study 2:
previously received visual training or visual stimulation according to the method of Hall and Bailey.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2008
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17734.100.07